II. Remarks and Arguments:

Claims 1-7, 9-10, 14-16, and 18-30 are pending. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

A. Rejection Under 35 U.S.C. § 103(a):

In the Office Action, the Examiner maintained his rejection of claims 1-7, 9, 10, 14-16 and 18-30 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,128,143 to Baichwal et. al. (hereinafter "the '143 patent") in view of U.S. Patent No. 5,472,712 to Oshlack et. al. (hereinafter "the '712 patent") and in further view of U.S. Patent No. 4,939,177 to Colombo (hereinafter "the '177 patent"). The Examiner stated that:

> "All of the patents are related in that they all disclose controlled or sustained release formulations. Baichwal discloses a tablet that comprises all of applicants claimed invention except for the use of a solid support, while Oshlack discloses a substrate that can be a tablet that is coated with a hydrophobic polymer (ethylcellulose) and Colombo discloses a support platform applied to a deposit core..., thus by combining the disclosures above one skilled in the art could make, on their own, the same invention as applicants... It would have been obvious to combine the above documents because there is always motivation to enhance the controlled release of a medicament, so that one skilled in the art could foresee that by combining the controlled release tablet in Baichwal and the controlled release coatings or solid support in Oshlack and Colombo the release rate of the dosage form could be further enhanced or modified."

Independent claim 1 of the present invention recites:

> 1. A method of preparing a bioavailable sustained release tablet comprising:
>
> combining (i) a medicament in amorphous form, (ii) a wetting agent and (iii) a sustained release excipient to obtain a mixture; said sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent, and an inert diluent, the ratio of inert diluent to gelling agent being from about 1:8 to about 8:1, said ionizable gel strength enhancing agent increasing the gel strength of a gel formed when said solid dosage form is exposed to environmental fluid, and said gelling agent comprising xanthan gum and locust bean gum in a ratio of from

about 1:3 to about 3:1;

thereafter drying and milling said mixture to obtain a sustained release tablet; applying a support platform to said tablet; and

forming said sustained release product into orally administrable unit doses.

A medicament is rendered into its amorphous form by solubilizing or dispersing the medicament in a vehicle, e.g., a solid solubilizing agent, prior to incorporation into the formulation (See: present specification, page 5, lines 24-26). Specific methods for rendering the drug in amorphous form include dispersing an insoluble medicament into a solid, water soluble carrier to form a solution or dispersion that is thereafter rendered solid to form a "solid solution" or a "solid dispersion" that provides improved solubility characteristics (Id. at page 9, lines 15-20. Other methods of rendering drug in amorphous form include manufacturing solid solutions or dispersions by i) a fusion method, which involves heating a physical mixture of medicament and carrier to a fluid state and subsequently cooling to room temperature; ii) co-precipitation or co-evaporation conducted by dissolving a medicament and carrier in a volatile organic solvent, followed by evaporation of the solvent, leaving a dispersion as a residue; and iii) a melting-solvent method conducted by dissolving medicament within a cosolvent, and mixing the resulting solutions with a molten carrier, followed by cooling of the fluid to room temperature (Id. at page 10, lines 1-8).

Applicants respectfully submit that the '143 patent does not teach or suggest the use of a medicament in amorphous form as claimed in the present invention. The '143 patent describes an excipient composition that may be mixed with a wide range of medicaments and directly compressed into a solid dosage form, without the aid of the usual pharmaceutical dry or wet binders, filers, disintegrants, and glidants (See: the '143 patent, col. 5, lines 57-62). The medicament utilized in the '143 patent is added directly to the excipient described therein via dry or wet granulation techniques (See: Examples 2-57). Nowhere does the "143 patent teach or suggest utilizing a medicament in amorphous form as claimed in independent claim 1 of the present invention.

The '712 patent is directed to controlled release substrates, wherein an active agent substrate(s) (e.g., tablet, spheroid (bead), microsphere, seed, pellet, or other multi-particulate system) is/are coated with an aqueous dispersion of a hydrophobic polymer, e.g., ethylcellulose, wherein the controlled release is caused by a coating of the substrate with the hydrophobic polymer (See: '712 patent at col. 3, lines 24-27). Nowhere does the '712 patent teach or suggest utilizing a medicament in amorphous form as claimed in independent claim 1 of the present invention.

The '177 patent is directed to a controlled release system comprising a deposit-core containing an active agent having a defined geometric form; and a support-platform applied to the deposit core, the deposit core containing mixed with the active agent a polymeric material having a high degree of swelling on contact with water or a aqueous liquid, a gullible polymeric material being replaceable by a single polymeric material having both swelling and gelling properties, as well as other adjuvants, the support platform consisting of a polymeric material insoluble in aqueous liquids and partially coating the deposit core. Nowhere does the '177 patent teach or suggest utilizing a medicament in amorphous form as claimed in independent claim 1 of the present invention.

In view of the arguments provided above, it is respectfully submitted that neither the '712 patent or the '177 patent can cure the deficiency of the '143 patent. Therefore, independent claim 1 of the present invention is not obvious over the '143 patent in view of the '712 patent or the '177 patent. As claims 2-7, 9, 10, 14-16 and 18-30 depend from claim 1, these claims are also not obvious over the '143 patent in view of the '712 patent or the '177 patent.

Applicants respectfully request that the Examiner's rejection be removed.

B. Double Patenting Rejection:

In the Office Action, the Examiner rejected claims 1-7, 9, and 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,048,548 in view of U.S. 4,839,177.

The Examiner also rejected claims 1-7, 9, 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,709,677 in view of U.S. 4,829,177 (Columbo).

Applicants respectfully submit that upon receipt of a Notice of Allowance indicating the present claims are otherwise allowable, the filing of a terminal disclaimer will be considered.

III. CONCLUSION:

Applicants respectfully submit that in view of the arguments made, the pending claims are in condition for allowance. An early and favorable action on the merits is earnestly solicited.

As Tuesday, January 2, 2007 was declared a Federal Holiday in view of President Ford's Funeral no fee is believed due for this submission. If it is determined that any fees are due, the Commissioner for Patents is hereby authorized to charge said fees to Deposit Account No. 50-0552.

Respectfully submitted,
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